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**Notice of Allowability**

Application No.

10/686,944

Examiner

Anand U Desai, Ph.D.

Applicant(s)

SCHULTZ ET AL.

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 3, 2004.
2. ☒ The allowed claim(s) is/are 1-21, 24, 25 and 58-60.
3. ☒ The drawings filed on 15 October 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance              |
|   | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on December 3, 2004. Claims 26-57 have been cancelled. New claims 58-60 have been added. Claims 1-25, and 58-60 are currently pending and are under examination.

#### **Withdrawal of Rejections**

2. The rejection of claims 1, 23-25 under the judicially created doctrine of obviousness-type double patenting over US2003/0082575 A1 is withdrawn based on Applicant's amendment to cancel the claims in the corresponding application.

3. The rejection of claims 1-25 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph is withdrawn.

4. The rejection of claims 1-7, 10-13, and 21 under 35 U.S.C. § 102(b) as being anticipated by Rodriguez et al. (J. Org. Chem 63(21): 7134-7135 (1998)) is withdrawn.

5. The rejection of claims 1-21 under 35 U.S.C. § 103(a) as being unpatentable over Rodriguez et al. (J. Org. Chem 63(21): 7134-7135 (1998)) in view of Palcic, M. (Methods in Enzymology, 230: 300-316 (1994)) and further in view of Kaushal, GP and Elbein, AD (Arch Biochem Biophys 250(1): 34-47 (1986), abstract) is withdrawn.

6. The rejection of claims 1-25 under 35 U.S.C. § 103(a) as being unpatentable over Rodriguez et al. (J. Org. Chem 63(21): 7134-7135 (1998)) in view of Palcic, M. (Methods in Enzymology, 230: 300-316 (1994)) further in view of Kaushal, GP and Elbein, AD (Arch Biochem Biophys 250(1): 34-47 (1986), abstract) and further in view of Wang, L. et al. (Science 292: 498-500 (2001)) is withdrawn.

**EXAMINER'S AMENDMENT**

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Jonathan Alan Quine on February 16, 2005.

**Examiner's Amendment to the Claims:**

1. (Currently Amended) A method for synthesis of a glycoprotein, the method comprising:

incorporating, in a cell translation system, an unnatural amino acid that comprises a first reactive group into a protein; wherein the incorporating step comprises incorporating the unnatural amino acid into the protein with an orthogonal tRNA/orthogonal aminoacyl-tRNA synthetase (O-tRNA/O-RS) pair, wherein the O-tRNA recognizes a selector codon and incorporates the unnatural amino acid into the protein in response to the selector codon, and wherein the O-RS aminoacylates the O-tRNA with the unnatural amino acid, and[[,]]

contacting the protein with a saccharide moiety that comprises a second reactive group, wherein the first reactive group reacts with the second reactive group to attach the saccharide moiety to the unnatural amino acid, thereby producing the glycoprotein.

22. (Cancel).

23. (Cancel).

24. (Currently Amended) The method of claim 23 1, wherein the O-RS comprises an amino acid sequence comprising any one of SEQ ID NO[.]: 1, 2, or 3.

25. (Currently Amended) The method of claim 23 1, wherein the O-tRNA comprises a <sup>Tyr</sup>mutRNA<sub>CUA</sub> (~~SEQ ID NO. 7~~) (SEQ ID NO: 7).

58. (Currently Amended) The method of claim 1, wherein incorporating the unnatural amino acid into the protein comprises aminoacylating an ~~O-tRNA~~ O-tRNA with an unnatural amino acid.

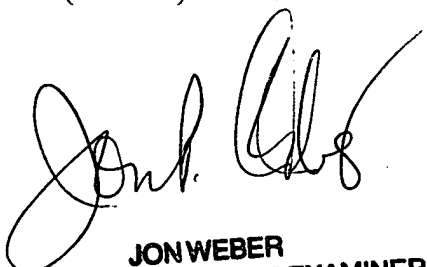
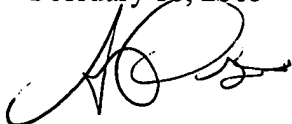
59. (Currently Amended) The method of claim 1, wherein incorporating the unnatural amino acid into the protein comprises: aminoacylating an ~~O-tRNA~~ O-tRNA with an unnatural amino acid, using an ~~ORS~~ O-RS, wherein the ~~ORS~~ O-RS aminoacylates the ~~O-tRNA~~ O-tRNA more efficiently than the ~~ORS~~ O-RS aminoacylates any endogenous tRNA of the translation system and wherein the ~~ORS~~ O-RS aminoacylates the ~~ORS~~ O-RS more efficiently with the unnatural amino acid than with a natural amino acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 16, 2005



**JON WEBER**  
SUPERVISORY PATENT EXAMINER